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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,347	11/14/2003	Joel Richard	017751-042	4071

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/714,347	RICHARD ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-15 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 4-15 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks, amendments, and Request for Continued Examination filed on 04/30/09 are acknowledged.

2. Claims 1, 3 and 16-20 were cancelled. Claims 2, 4-10 and 14 were amended. New claims 21-27 were added.

3. Claims 2, 4-15 and 21-27 are included in the prosecution.

Continued Examination under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/30/09 has been entered.

Response to Arguments

Rejection of claims 1-2, 4, 7-13, 15, 17-18 and 20 under 35 USC § 103(a)

5. Applicant's arguments, see Page 7, filed 04/30/09, with respect to the rejection of claims 1-2, 4, 7-13, 15, 17-18 and 20 under 35 U.S.C. 103(a) as being unpatentable over Yajima et al. JP 05-309261, in view of Gillberg-Laforce et al. (US 5,618,622) and Ezpeleta et al. (International Journal of Pharmaceutics, 131 (1996) 191-200) have been fully considered and are persuasive in part.

Applicant argues that the '261 reference requires the use of an organic component, e.g., ethanol (¶ 0005). New claim 21 does not exclude the organic solvent and organic acid, therefore, the obviousness rejection with respect to this reference will be maintained. New claim 22 specifically excludes the organic solvent and organic acid, thereby removing the '261 reference.

Regarding the Gillberg-LaForce reference ("GL"), Applicant argues that it is nonanalogous art, and there has been no showing that one skilled in the art seeking to make microcapsules by complex coacervation would have turned to "GL" for any teaching, much less that relied on here; nor has there been any showing that one skilled in the art would have combined the particular statements and/or reagents of GL with those of the '261 reference, or that they would have done so in such a way as to arrive at the claimed subject matter.

Regarding the Ezpeleta reference, Applicant argues that the gliadin nanoparticles are prepared by a desolvation method and that Ezpeleta does not teach or suggest that the use of glutaraldehyde in an effort to cross-link particles resulting from those organic phase fabrication processes could have facilitated an all-aqueous fabrication method.

This was found persuasive. Therefore the rejection of 11/03/08 is withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yajima et al. JP 05-309261, in view of Soeda et al. (US 6,475,542 B1).

Rejection of claims 5-6 under 35 USC § 103(a)

Applicant's arguments, see Page 7, filed 04/30/09, with respect to the rejection of claims 5-6 under 35 U.S.C. 103(a) as being unpatentable over Yajima et al. JP 05-

309261, in view of Gillberg-Laforce et al. (US 5,618,622), Ezpeleta et al. (International Journal of Pharmaceutics, 131 (1996) 191-200) and Kangas et al. (US 3,843,585) have been fully considered and are persuasive. Therefore the rejection of 11/03/08 is withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yajima et al. JP 05-309261, in view of Soeda et al. (US 6,475,542 B1).

Rejection of claim 14 under 35 USC § 103(a)

Applicant's arguments, see Page 7, filed 04/30/09, with respect to the rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Yajima et al. JP 05-309261, in view of Gillberg-Laforce et al. (US 5,618,622), Ezpeleta et al. (International Journal of Pharmaceutics, 131 (1996) 191-200) and Lee et al. (Journal of Applied Polymer Science, Vol. 63, Issue 4, 425-432) have been fully considered and are persuasive. Therefore the rejection of 11/03/08 is withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Yajima et al. JP 05-309261, in view of Soeda et al. (US 6,475,542 B1) and Lee et al. (Journal of Applied Polymer Science, Vol. 63, Issue 4, 425-432) .

Claim Objections

6. Claim 21 is objected to because of the following informalities: There is a typographical error in claim 21, part (c). The term "polyectrolyte" should be corrected to recite "polyelectrolyte". Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 4-13, 15 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima et al. JP 05-309261, in view of Soeda et al. (US 6,475,542 B1).

The claimed invention is a method for producing microcapsules of a material comprising: (a) solubilizing a plant protein in an aqueous medium at pH 2-7; (b) centrifuging the solubilized plant protein to obtain a supernatant and a pellet; (c) extracting the supernatant and mixing it with an aqueous polyelectrolyte solution wherein the polyelectrolyte in the resulting aqueous medium has a charge opposite the plant protein; and (d) coacervating the supernatant and polyelectrolyte mixture with a material to form a complex coacervate of the plant protein and the polyelectrolyte encapsulating the material.

Yajima teaches the manufacture method of a microcapsule (Detailed Description, [0001]). A polycationic wall material and a polyanionic wall material are subjected to complex coacervation to produce microcapsules (Abstract). The complex coacervation method is disclosed (Detailed Description, [0002]). Wheat gluten extract is used as the poly cation wall membrane material in a microcapsule made by complex coacervation (Detailed Description, [0004]). Polyanion wall materials such as gum arabic, sodium alginate, and agar are disclosed (Detailed Description, [0008]).

Yajima does not expressly teach cationic polyelectrolytes or the use of glutaraldehyde as a crosslinking agent for hardening the microcapsules.

Soeda teaches that "complex coacervation consists in coacervation (phase separation) induced by the electrolytical action between polycations and polyanions, which causes separation of a polymer rich phase out of the equilibrium liquid with subsequent precipitation and adsorption around surface of the droplets of a hydrophobic core substance to form a capsule wall" (Col. 1, lines 56-62). The process of encapsulation by complex coacervation is outlined where "1) A hydrophobic core substance is emulsified or dispersed in a positively charged water-soluble polymer solution having the properties of a protective colloid. 2) An oppositely charged hydrophilic colloid solution is added thereto. 3) The colloid concentration, pH, temperature and the like of the system are controlled so as to induce coacervation (phase separation), thereby to precipitate a colloid rich phase of the water-soluble polymer onto the surface of the hydrophobic core substance to form a microcapsule wall. 4) The capsule wall of the resulting microcapsules is insolublized and stabilized by crosslinking. In the step of insolublizing the capsule wall, aldehydes, such as formaldehyde, glutaraldehyde and the like, are generally used as a crosslinking agent for hardening … tannic acid, gallic acid and the like are known as a crosslinking agent for hardening applicable to foods …"(Col. 2, lines 1-16). Edible proteins used in the capsule wall include soybean protein and corn protein (Col. 4, lines 37-44). Gum arabic and CMC Na are disclosed as the polyanions used in complex coacervation (Col. 4, lines 16-19). Quaternary ammonium salts (ammonium chloride and ammonium sulfate) are disclosed as the edible salts used in the process of encapsulation (Col. 4, lines 46-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a microcapsule with wheat protein extract by complex coacervation, as suggested by Yajima, combine it with the process of complex coacervation that includes edible plant proteins such as soybean protein and corn protein, gum arabic and CMC Na as the polyanions, quaternary ammonium salts as the edible salts, and glutaraldehyde as the crosslinking agent, as taught by Soeda, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the process of complex coacervation by using non-gelatin, plant proteins such as wheat protein, soybean protein, and corn protein is known in the art, as evidenced by the teachings of Yajima and Soeda. One of ordinary skill in the art would use the crosslinking agents, polyanions and cations disclosed by Soeda in the microcapsules of Yajima with a reasonable expectation of success in producing a functional plant protein based coacervate.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 21, the limitation of a method for producing microcapsules of a material comprising: (a) solubilizing a plant protein in an aqueous medium at pH 2-7 would have been obvious over the complex coacervation used to

produce gluten microcapsules as taught by Yajima (Abstract) in view of the water-soluble polymer solution having the properties of a protective colloid (Col. 2, lines 1-16) and over the plant proteins used in the capsule wall (including soybean protein and corn protein), as taught by Soeda (Col. 4, lines 37-44). The limitation of (b) centrifuging the solubilized plant protein to obtain a supernatant and a pellet would have been obvious over the continuous agitation process disclosed by Soeda (Col. 1, lines 65-67). The limitation of (c) extracting the supernatant and mixing it with an aqueous polyelectrolyte solution wherein the polyelectrolyte in the resulting aqueous medium has a charge opposite the plant protein would have been obvious over the addition of an oppositely charged hydrophilic colloid solution, as taught by Soeda (Col. 2, lines 4-5). The limitation of (d) coacervating the supernatant and polyelectrolyte mixture with a material to form a complex coacervate of the plant protein and the polyelectrolyte encapsulating the material would have been obvious over the coacervation (phase separation) step used by Soeda (Col. 2, lines 6-9).

Regarding instant claims 2, 11-13, 23 and 27, the hardening of the microcapsules after coacervating would have been obvious over the use of formaldehyde, glutaraldehyde and tannic acid used as crosslinking agents for hardening, as taught by Soeda (Col. 2, lines 1-16).

Regarding instant claim 4, the limitation of adding plant protein to the supernatant of step (b) followed by centrifuging the resultant mixture to obtain increased plant protein in the supernatant would have been obvious over the process taught by Soeda which includes controlling the concentration of the wall forming colloid (Col. 2, lines 6-

10). Moreover, during the process of routine optimization one of ordinary skill in the art would modify the level of plant protein in the supernatant in order to optimize the desired size or thickness of the microcapsules as well as to optimize the stability of the microcapsules with the desired material to be encapsulated.

Regarding instant claim 5, the limitation of carrying out the solubilizing step at a pH below the isoelectric pH of the plant protein would have been obvious over the process taught by Soeda which includes controlling the pH of the system so as to induce coacervation (phase separation) (Col. 2, lines 1-16).

Regarding instant claim 6, the limitation of carrying out the solubilizing step at a pH above the isoelectric pH of the plant protein would have been obvious over the process taught by Soeda which includes controlling the pH of the system so as to induce coacervation (phase separation) (Col. 2, lines 1-16).

Regarding instant claims 7-8 and 24, the plant protein would have been obvious over the wheat protein used in coacervated microcapsules as taught by Yajima (Abstract) and over the edible proteins used in the capsule wall including soybean protein and corn protein, as taught by Soeda (Col. 4, lines 37-44).

Regarding instant claims 9 and 25, the cationic polyelectrolyte would have been obvious over the quaternary ammonium salts ammonium chloride and ammonium sulfate taught by Soeda (Col. 4, lines 46-60).

Regarding instant claims 10 and 26, the anionic polyelectrolyte would have been obvious over the gum arabic and CMC Na taught by Soeda (Col. 4, lines 16-19).

Regarding instant claim 15, the microcapsules would have been obvious over the microcapsules taught by Yajima (Abstract) and by the microcapsules taught by Soeda (Col. 2, lines 1-16).

Regarding instant claim 22, the limitation of the absence of organic solvent and an organic acid would have been obvious over the aqueous solution of a protein taught by Soeda in view of the plant proteins that are also disclosed by Soeda as forming the microcapsule wall (Col. 5, lines 48-49 and Col. 4, lines 37-44).

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima et al. JP 05-309261, in view of Soeda et al. (US 6,475,542 B1) and Lee et al. (Journal of Applied Polymer Science, Vol. 63, Issue 4, 425-432).

The teachings of Yajima and Soeda are stated above.

Yajima and Soeda do not expressly teach chitosan as the cationic polyelectrolyte and acetic anhydride as the hardening agent.

Lee teaches hardening microcapsules containing the cationic polyelectrolyte chitosan (Abstract and Page 427, left hand column). Lee teaches that “chitosan, a cationic polysaccharide, was … deacylated … and followed by a homogenous reacylation with acetic anhydrides” (Abstract). It is further taught that polyelectrolyte complexes are formed when chitosan is complexed with an anionic polysaccharide (like sodium alginate) and drug microencapsulation was the application of the polyelectrolyte complexes produced (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a microcapsule with wheat protein extract by complex coacervation, as suggested by Yajima, combine it with the process of complex coacervation that includes edible plant proteins such as soybean protein and corn protein, gum arabic and CMC Na as the polyanions, quaternary ammonium salts as the edible salts, and glutaraldehyde as the crosslinking agent, as taught by Soeda, further combine it with the use of acetic anhydride and chitosan, as taught by Lee, and produce the instant invention.

One of ordinary skill in the art would have done this because the addition of acetic anhydride allows the reacylation of chitosan (as taught by Lee), which further cross links or “hardens” the resultant microcapsule.

Regarding instant claim 14, the limitation of chitosan and acetic anhydride would have been obvious over the chitosan and acetic anhydride taught by Lee (Abstract).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615